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(12) **United States Patent**
McGinley et al.

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(45) **Date of Patent: Aug. 20, 2024**

(54) **ANKLE REPLACEMENT SYSTEM AND METHOD**

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(73) Assignee: **WRIGHT MEDICAL TECHNOLOGY, INC.**, Memphis, TN (US)

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A61B 17/15 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/1682*** (2013.01); ***A61B 17/15*** (2013.01); ***A61B 17/17*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/1682; A61F 2/4684; A61F 2002/4205
See application file for complete search history.

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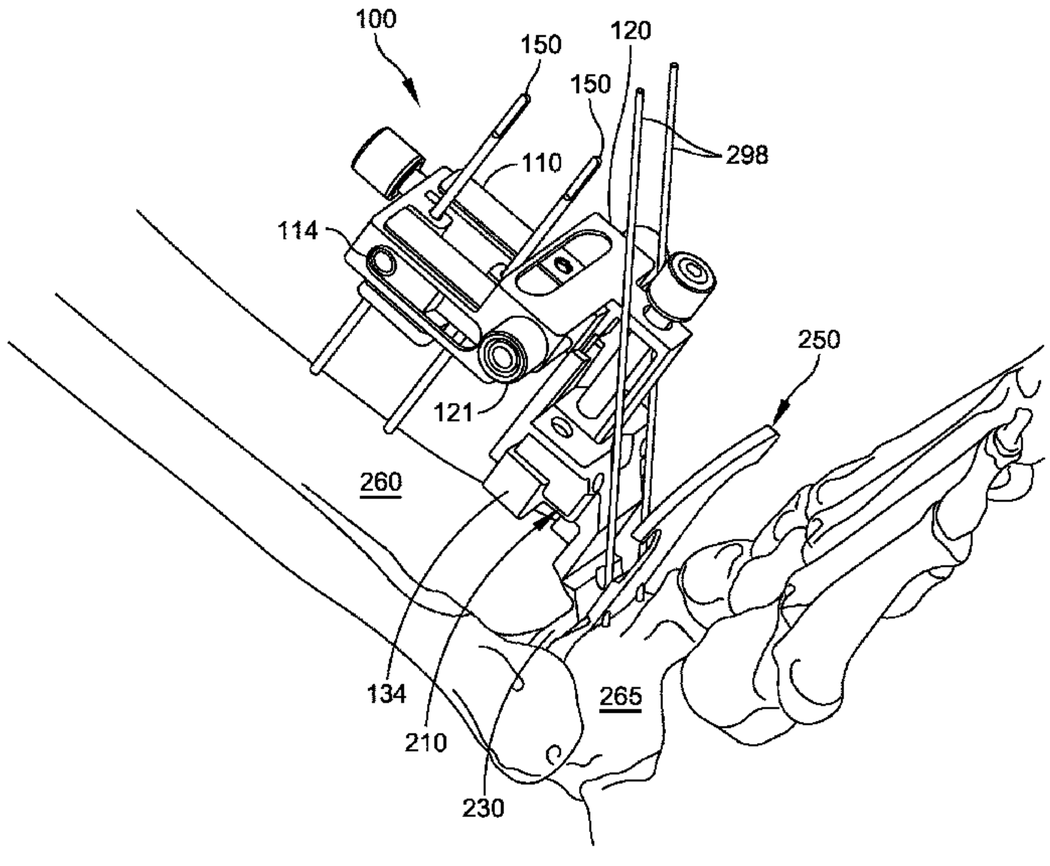
(57) **ABSTRACT**

A position adjustment device having a tool holder is locked to at least two pins projecting from respective anterior facing locations near a distal end of a tibia of a patient. The position adjustment device is adjusted. The position adjustment device is locked with the tool holder at first coordinates in the proximal-distal and medial-lateral directions. The distal end of the tibia is resectioned with a tool positioned on the tool holder, while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions. The tool is removed from the tool holder. A tibia trial is placed on the resectioned tibia using the tool holder, while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions. The tibia trial has a size and shape of a tibial tray of an ankle replacement system.

27 Claims, 17 Drawing Sheets



Related U.S. Application Data

continuation of application No. 15/335,949, filed on Oct. 27, 2016, now Pat. No. 10,321,922, which is a division of application No. 14/100,799, filed on Dec. 9, 2013, now Pat. No. 9,480,571.

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(51) **Int. Cl.**

A61B 17/17	(2006.01)
A61F 2/42	(2006.01)
A61F 2/46	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/4202*** (2013.01); ***A61F 2/4684*** (2013.01); *A61B 17/1775* (2016.11); *A61F 2002/4205* (2013.01)

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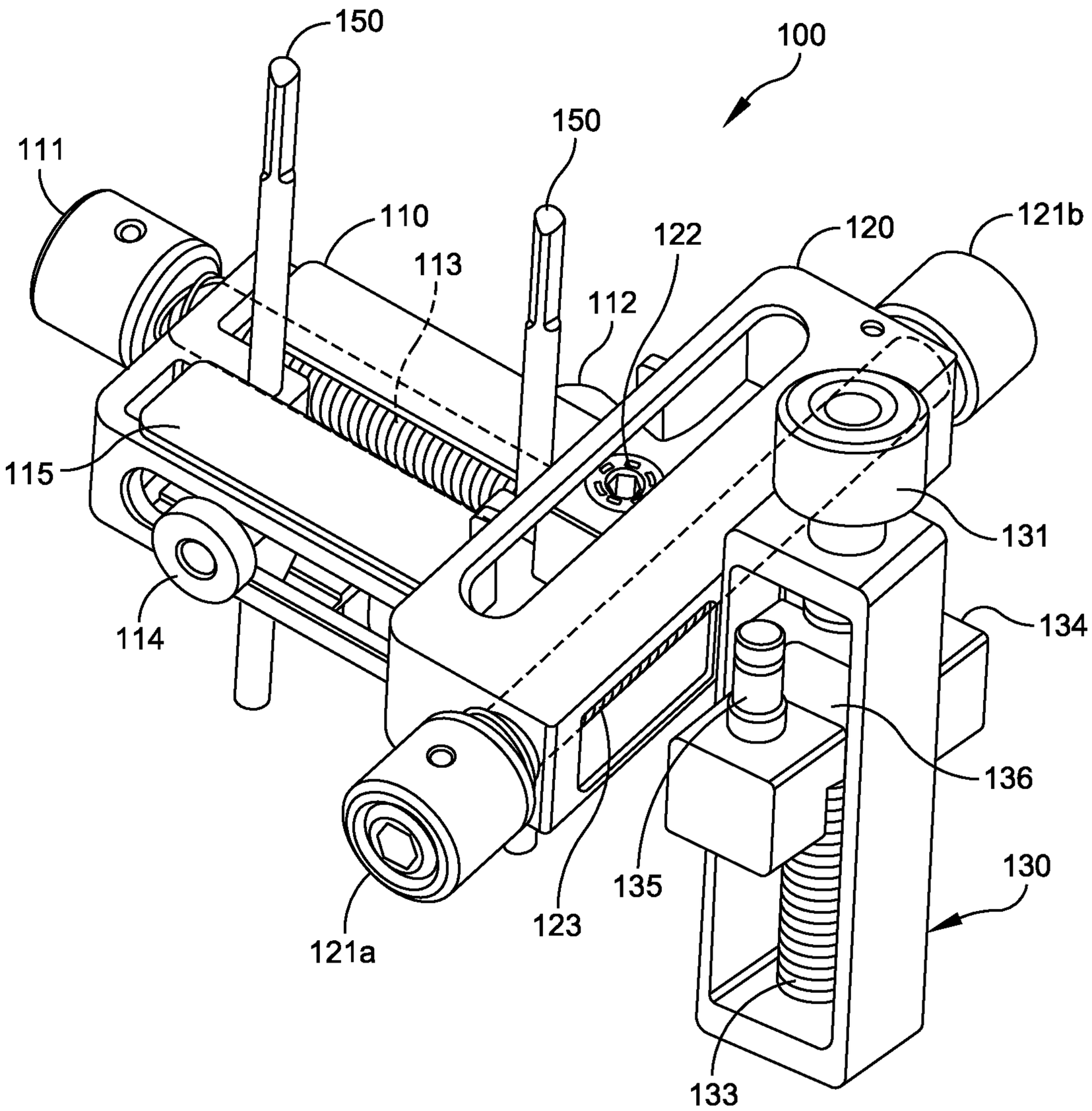
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121a
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FIG. 1

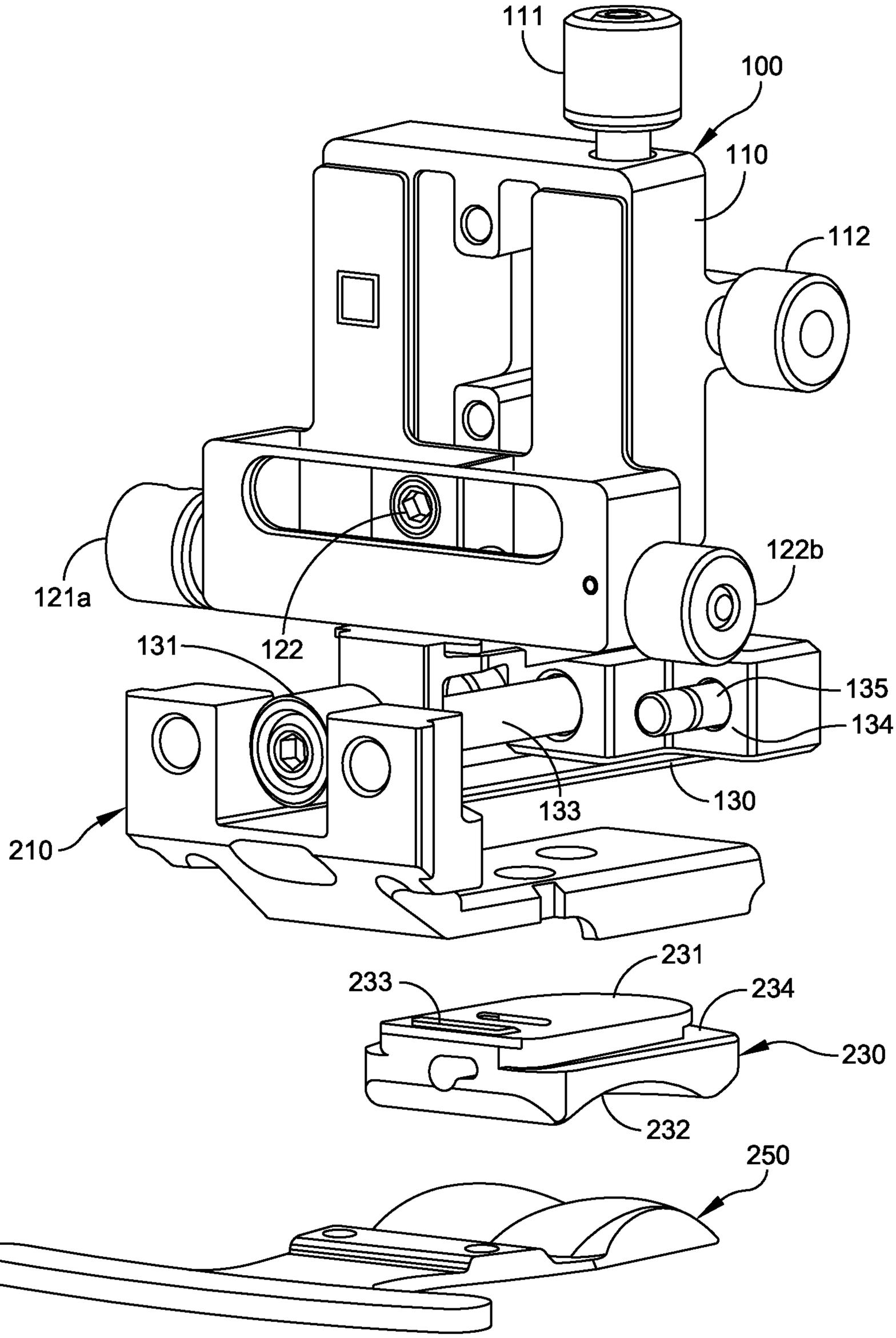
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FIG. 2

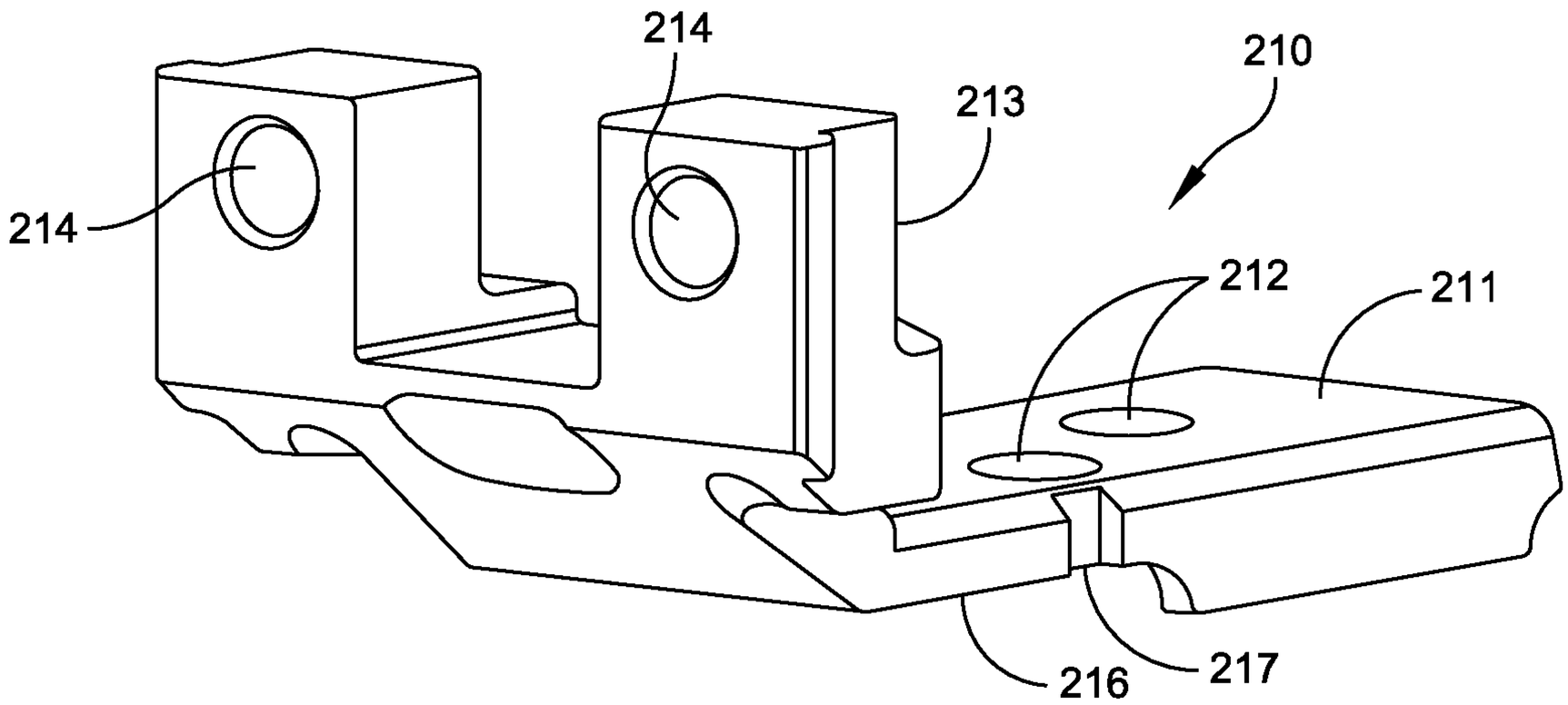

FIG. 3

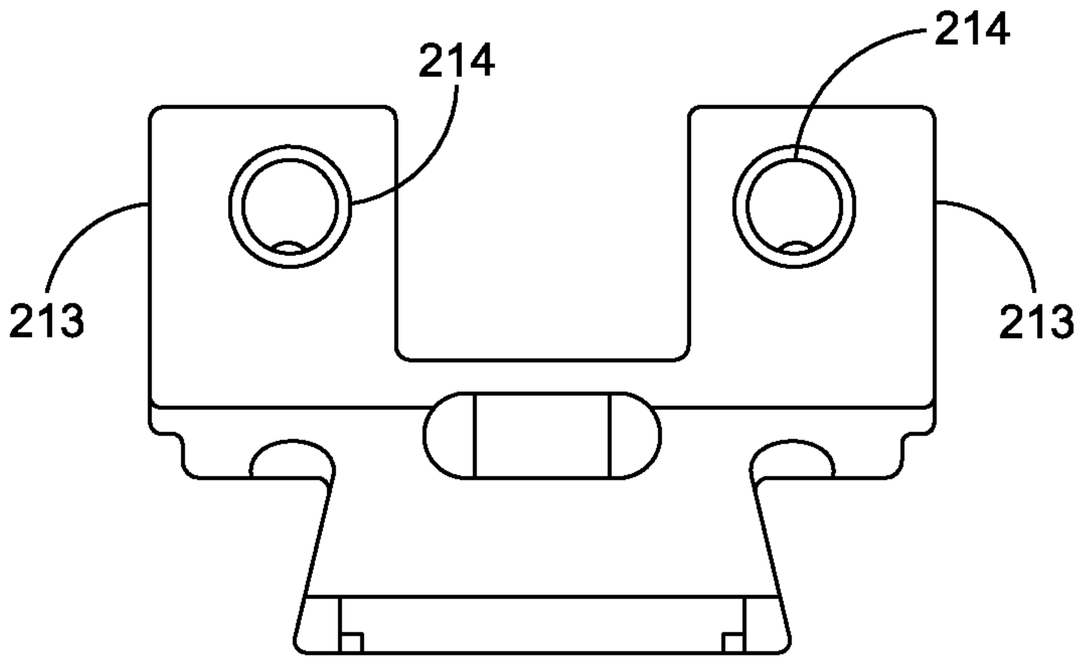

FIG. 4

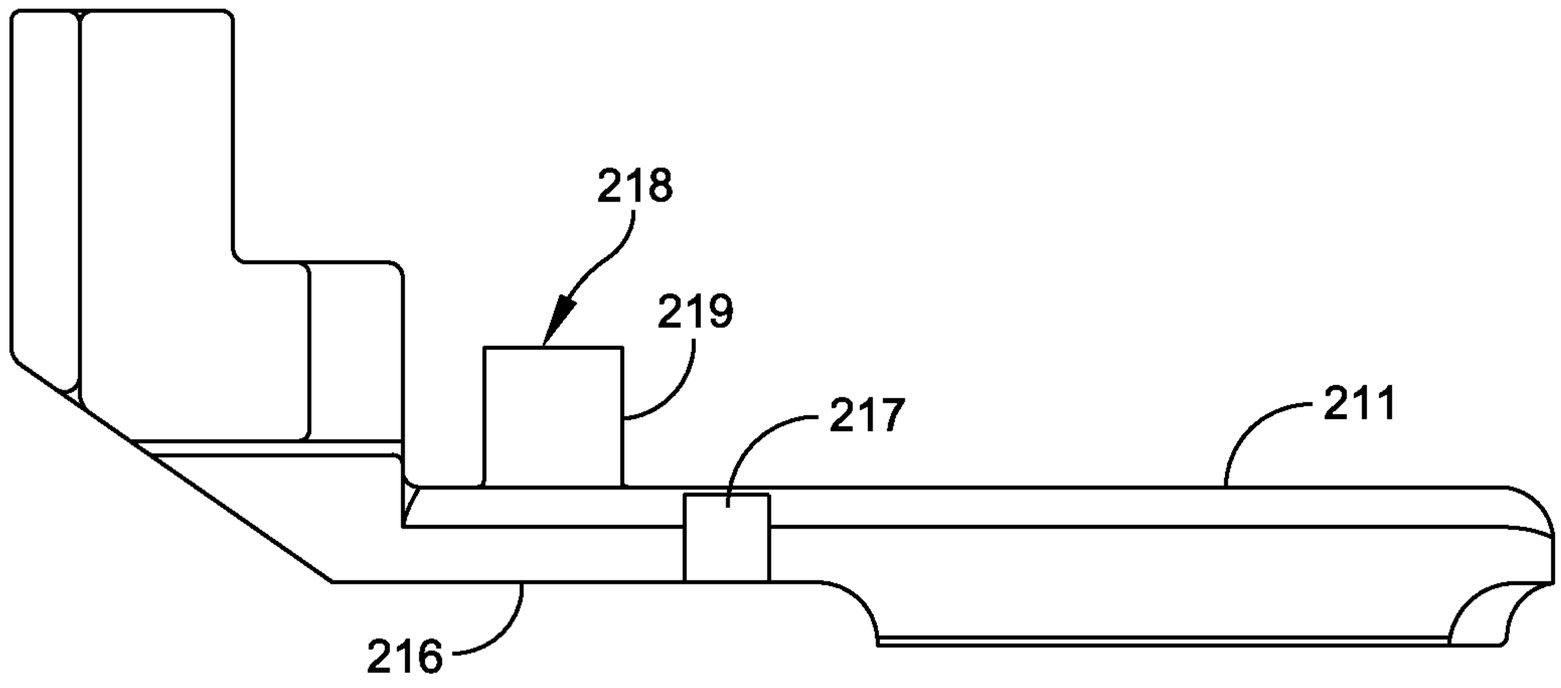

FIG. 5

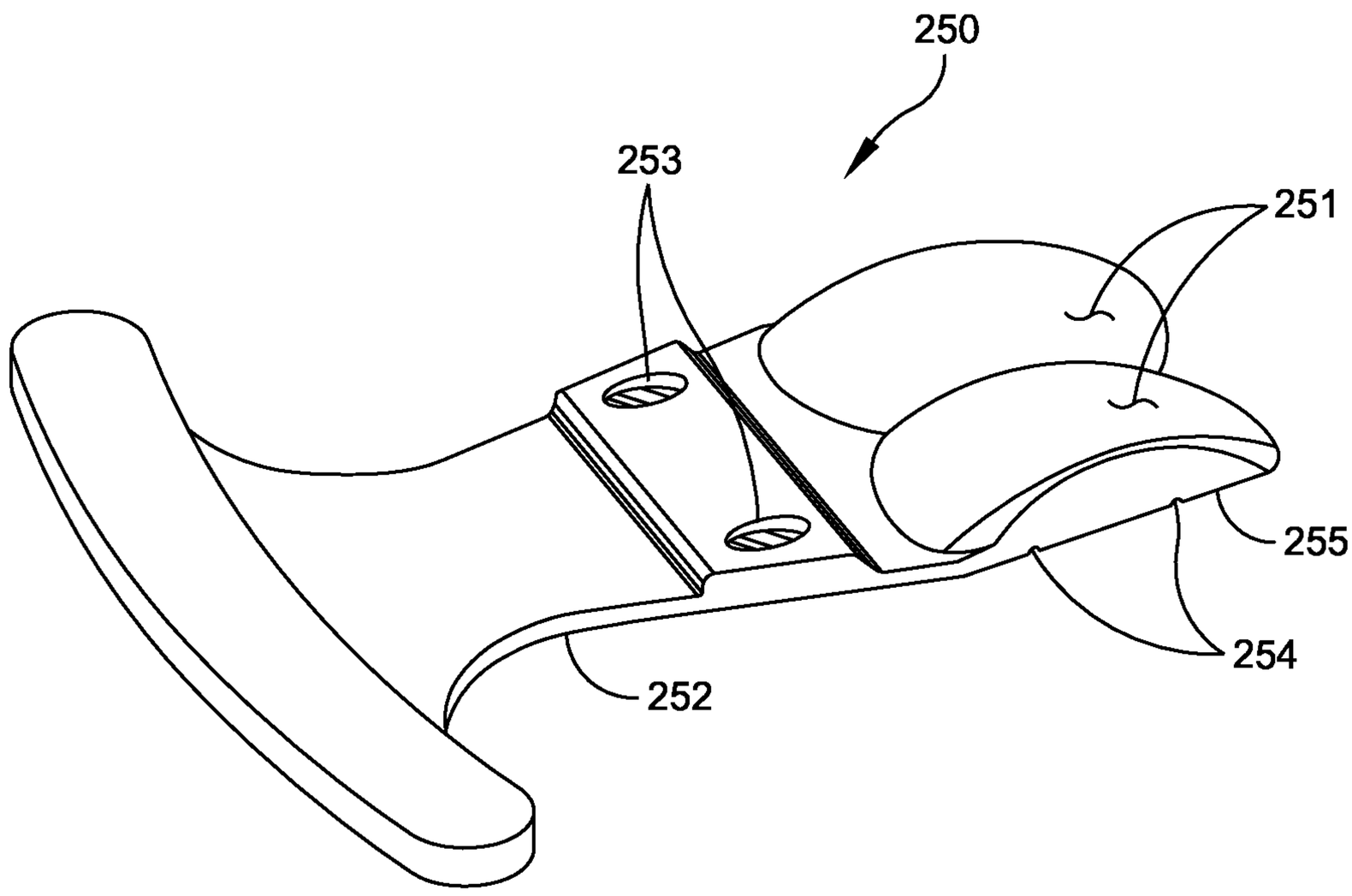

FIG. 6

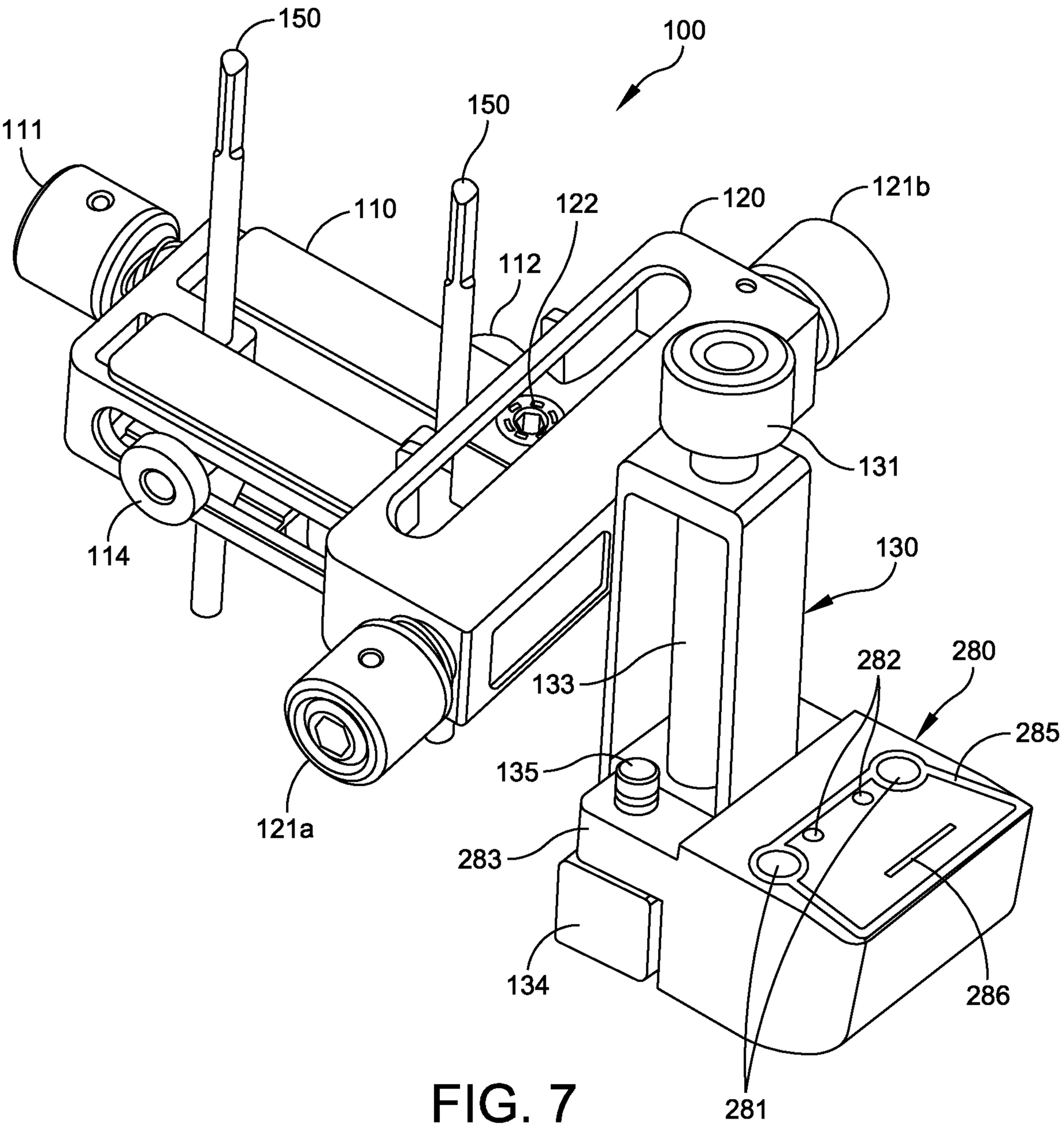
150
100
111
150
110
122
120
121b
112
131
114
130
133
282
280
285
135
121a
283
134
286
281

FIG. 7

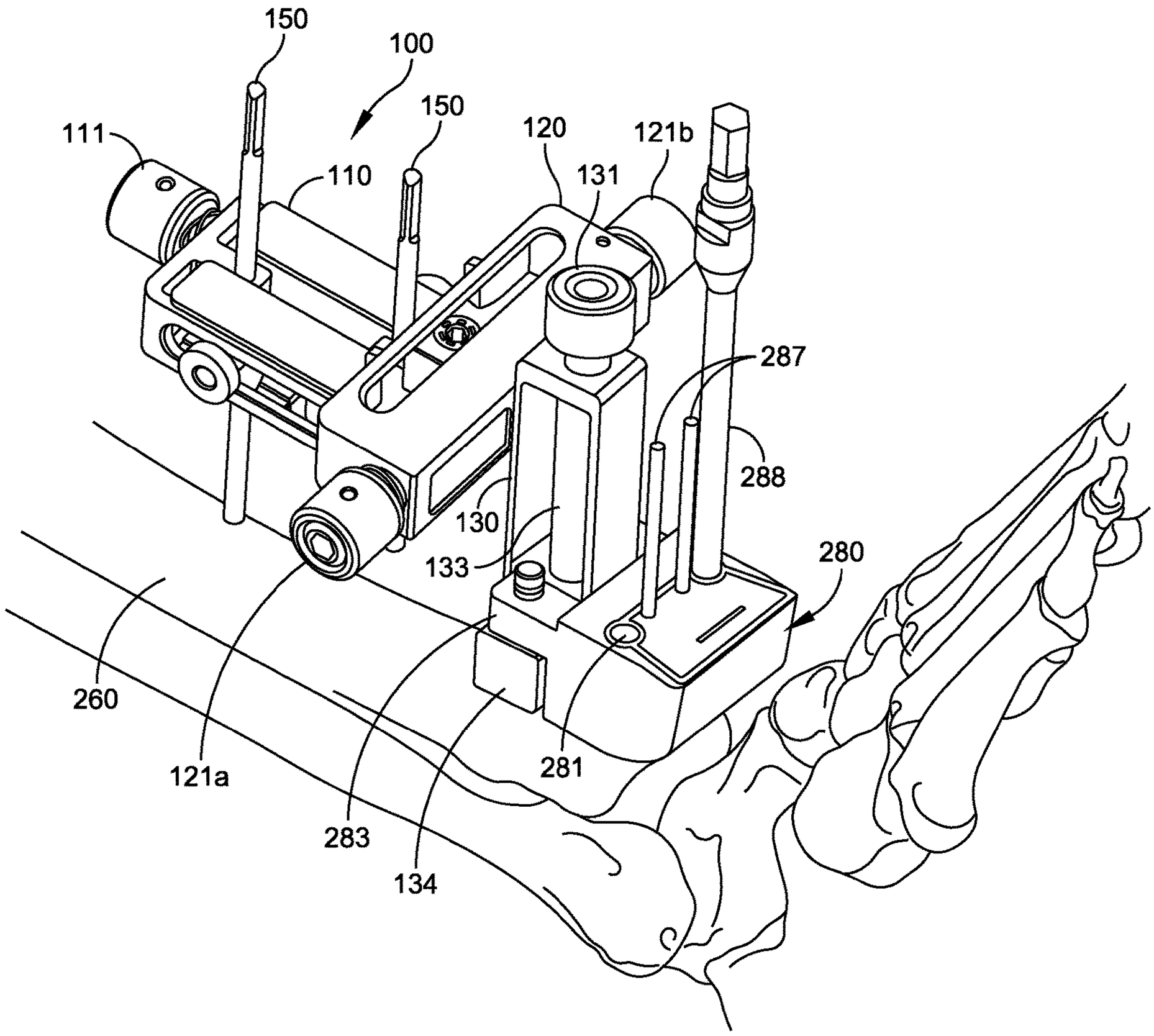
150
100
150
111
110
120
131
121b
287
288
130
133
280
260
121a
281
283
134

FIG. 8

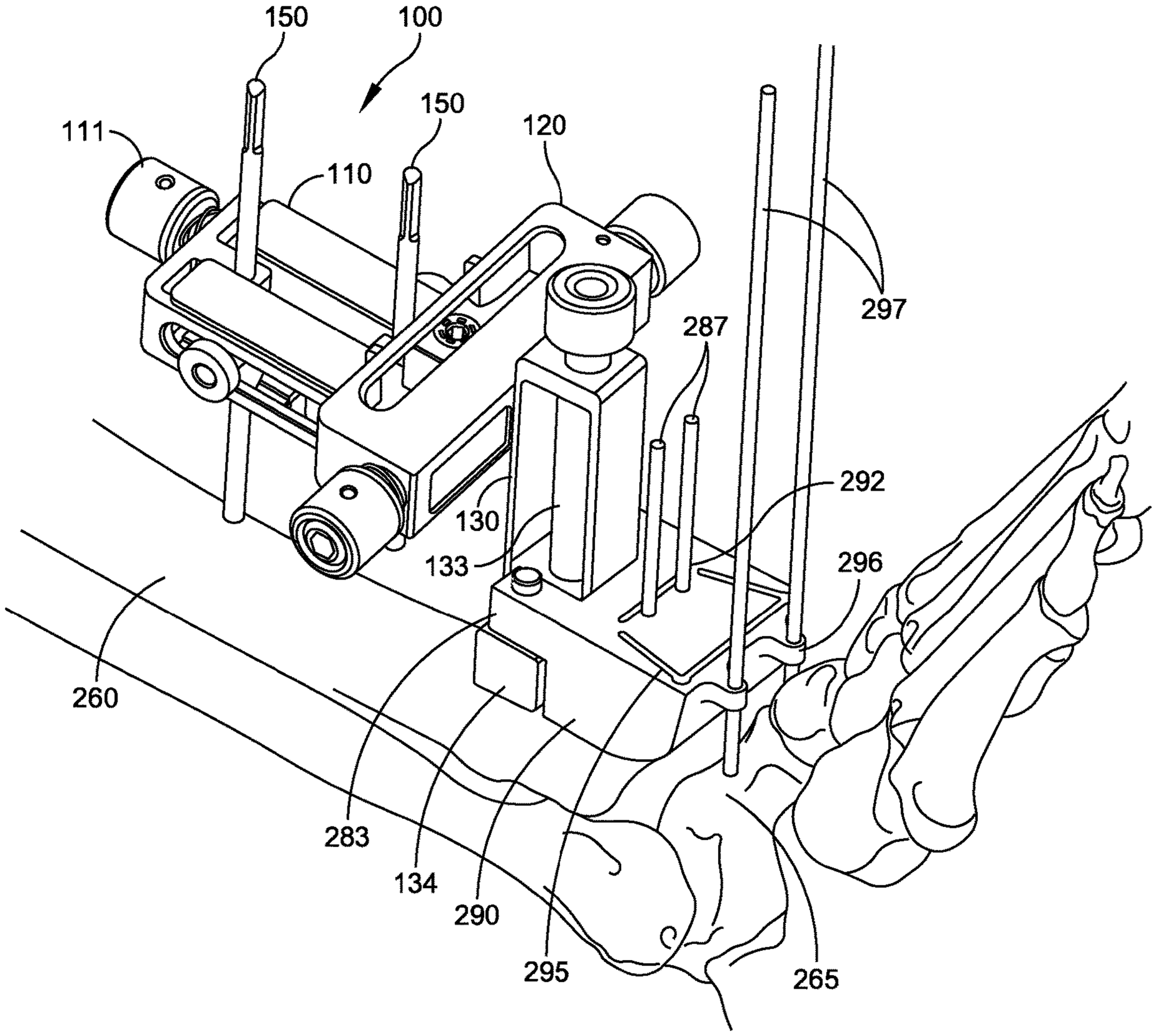
150
100
150
111
120
110
297
287
292
130
133
296
260
283
134
290
295
265

FIG. 9

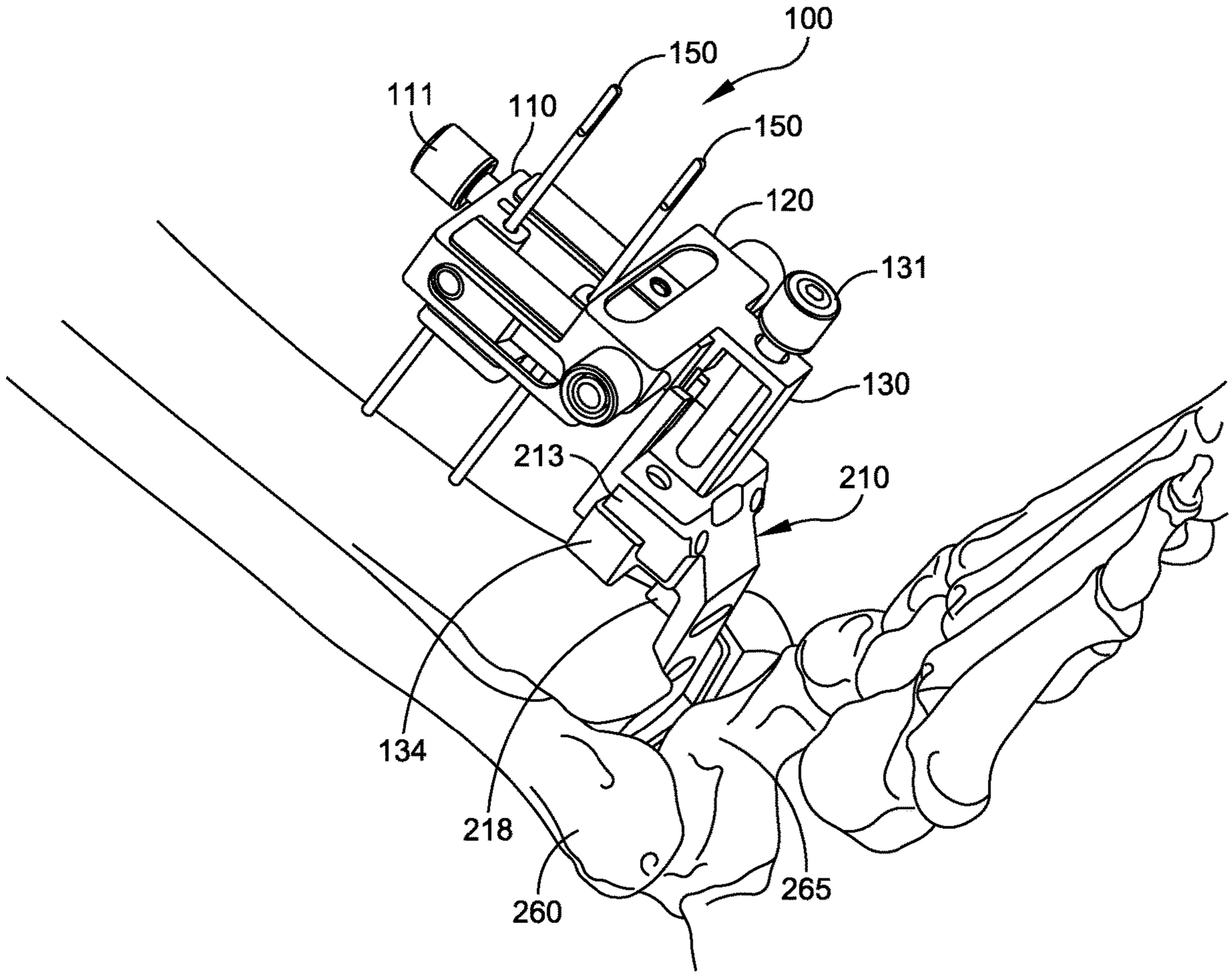

FIG. 10

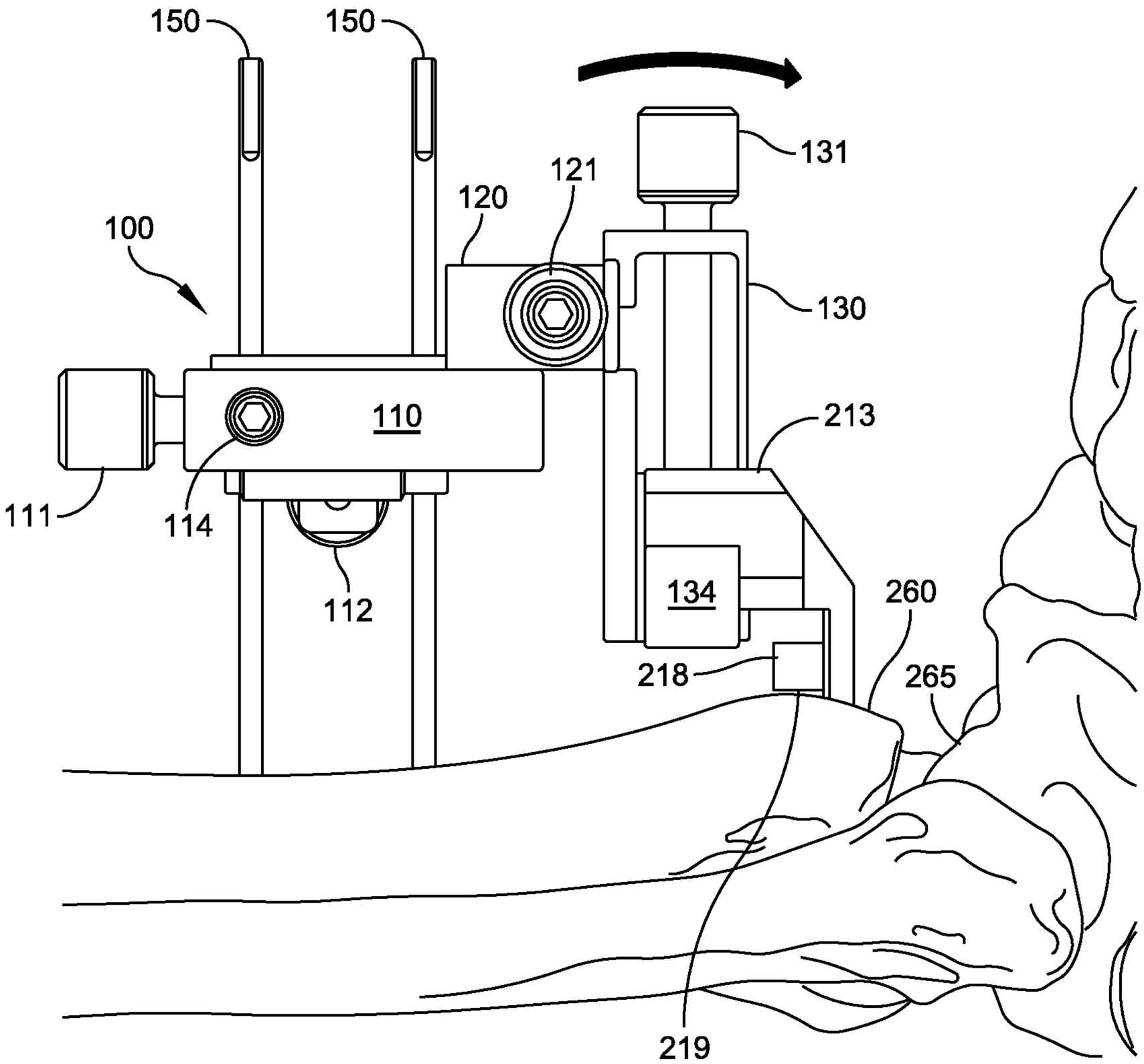
150
150
131
121
120
100
130
110
213
111
114
112
134
260
218
265
219

FIG. 11

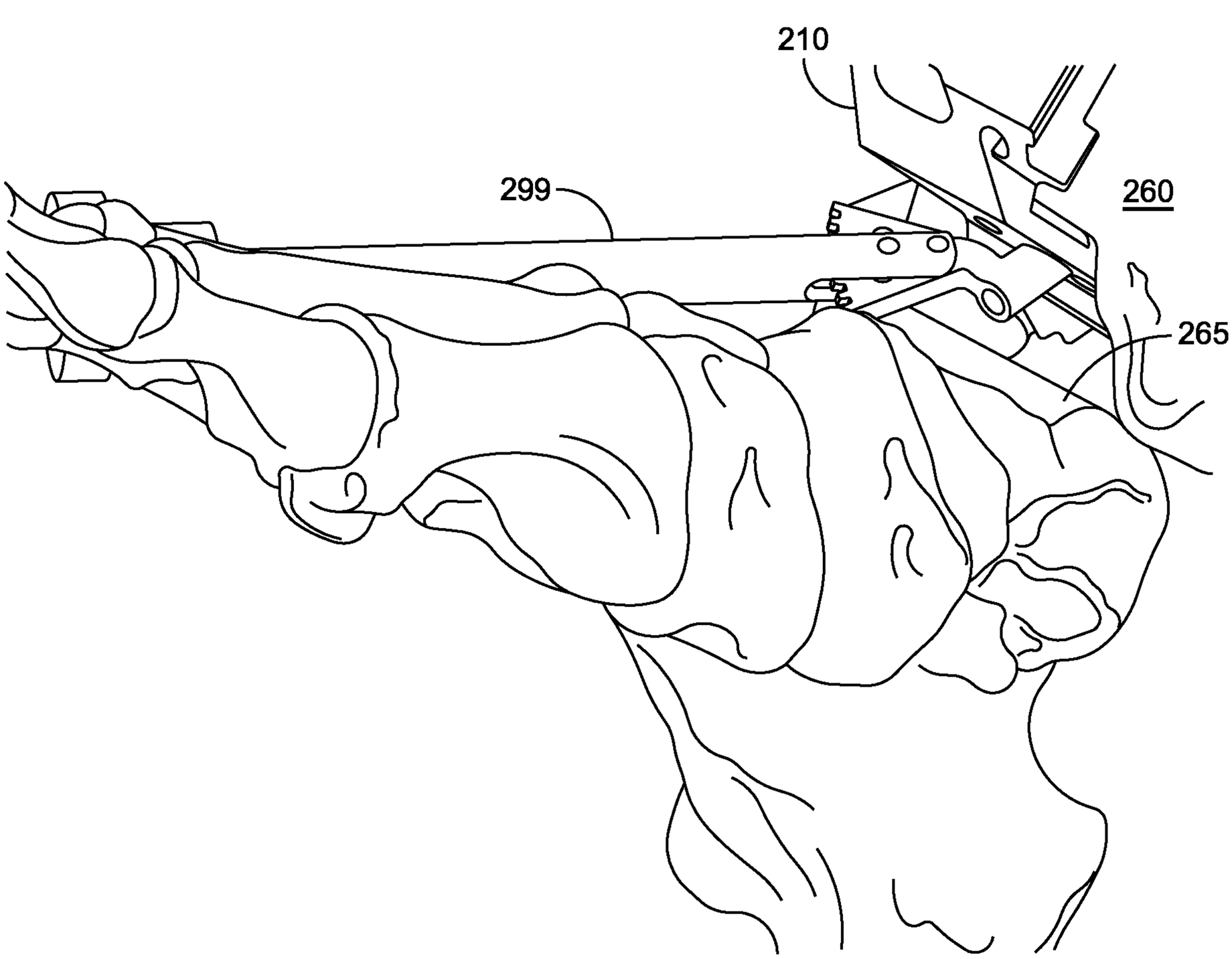

FIG. 12

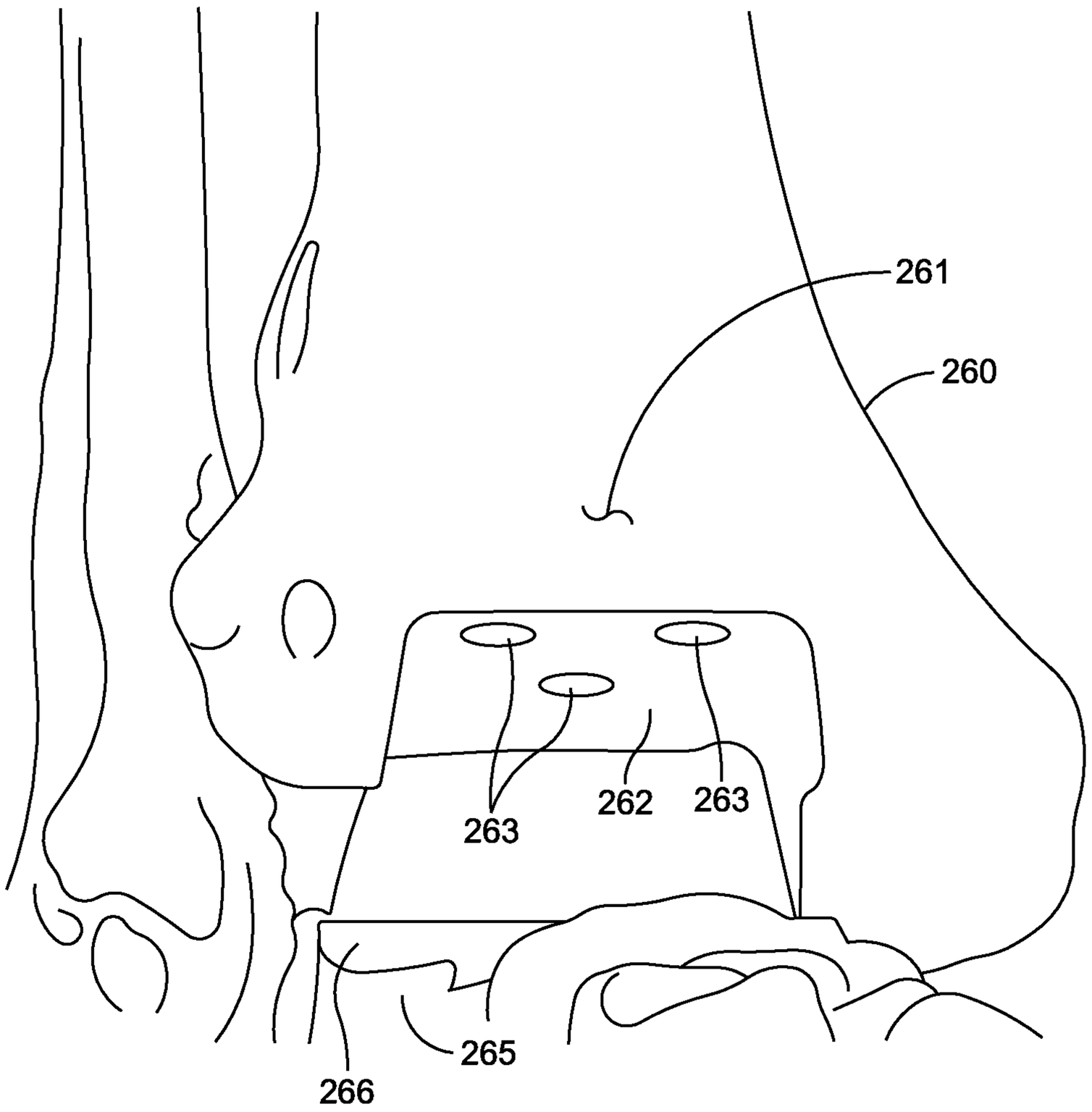

FIG. 13

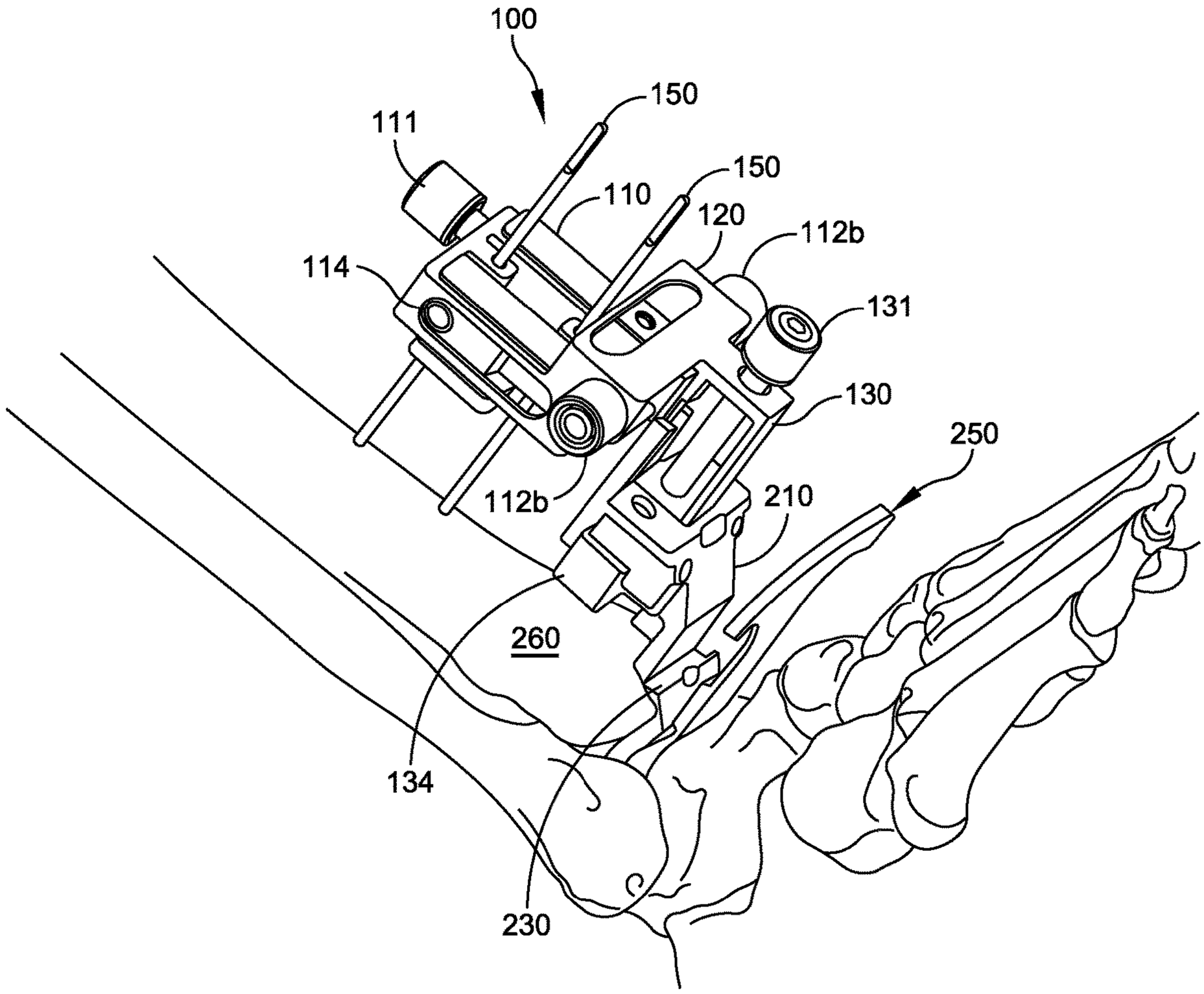
100
150
111
150
110
120
112b
114
131
130
250
112b
210
260
134
230

FIG. 14

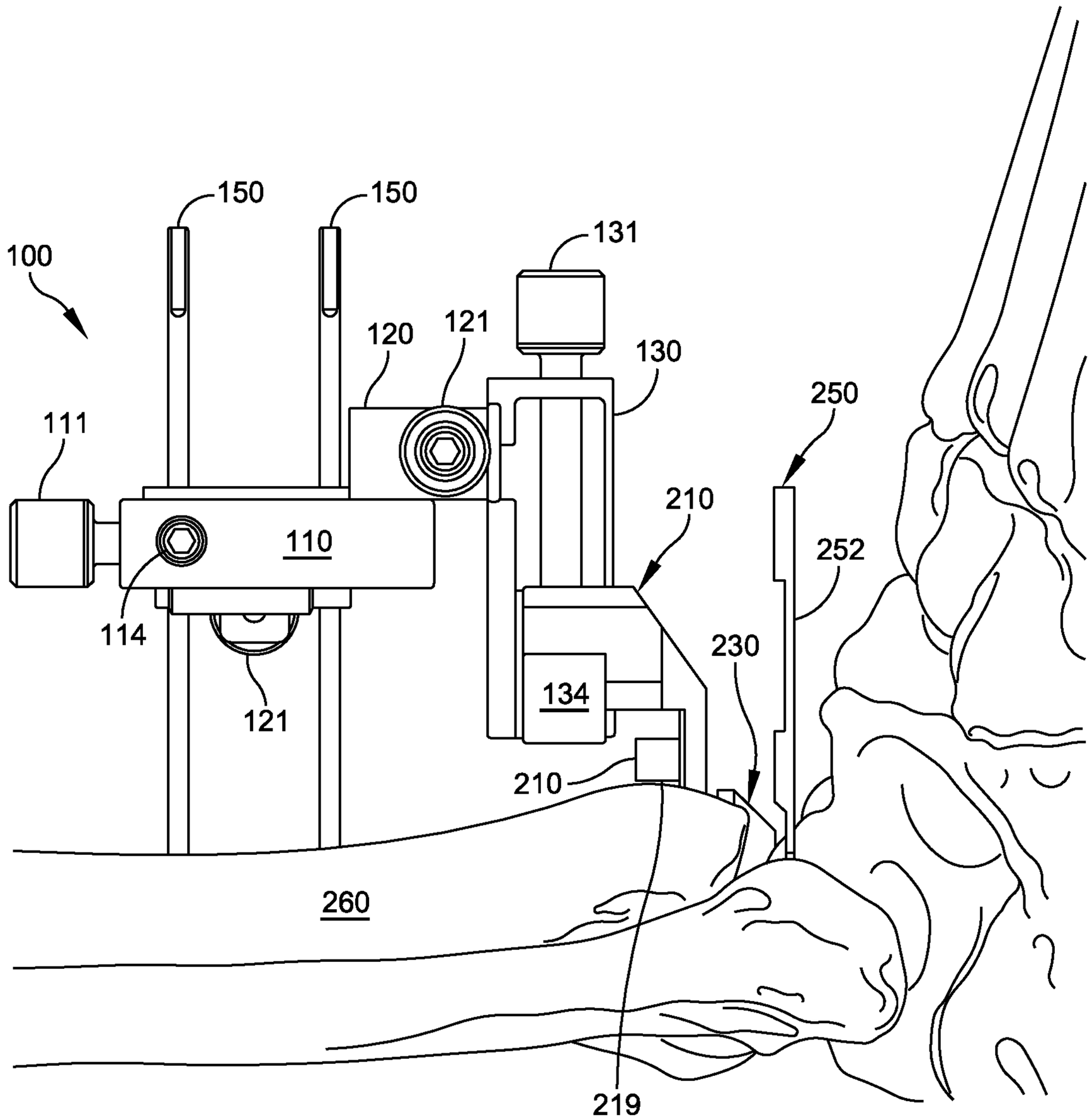
100
150
150
131
120
121
130
111
110
114
121
250
210
252
230
134
210
260
219

FIG. 15

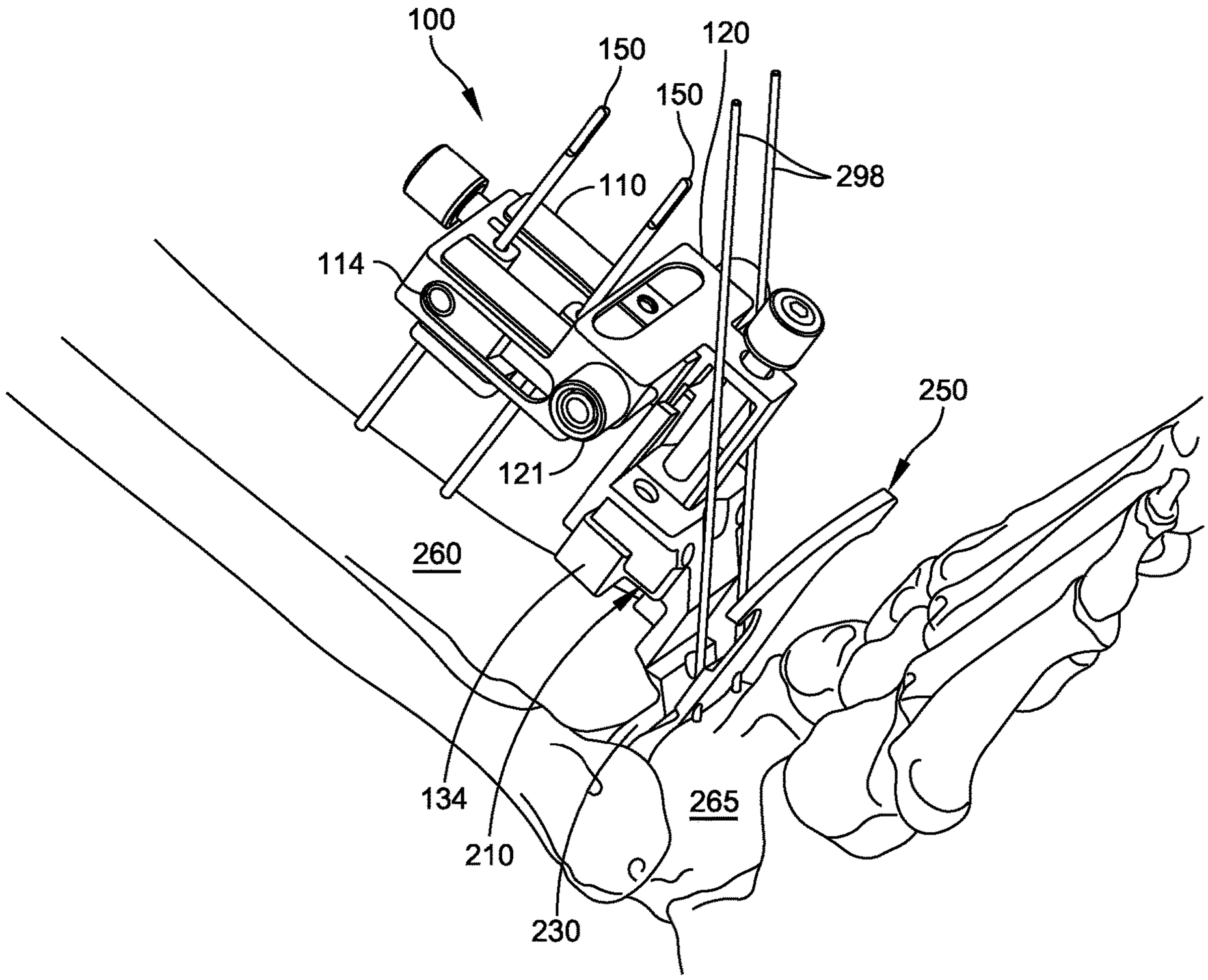

FIG. 16

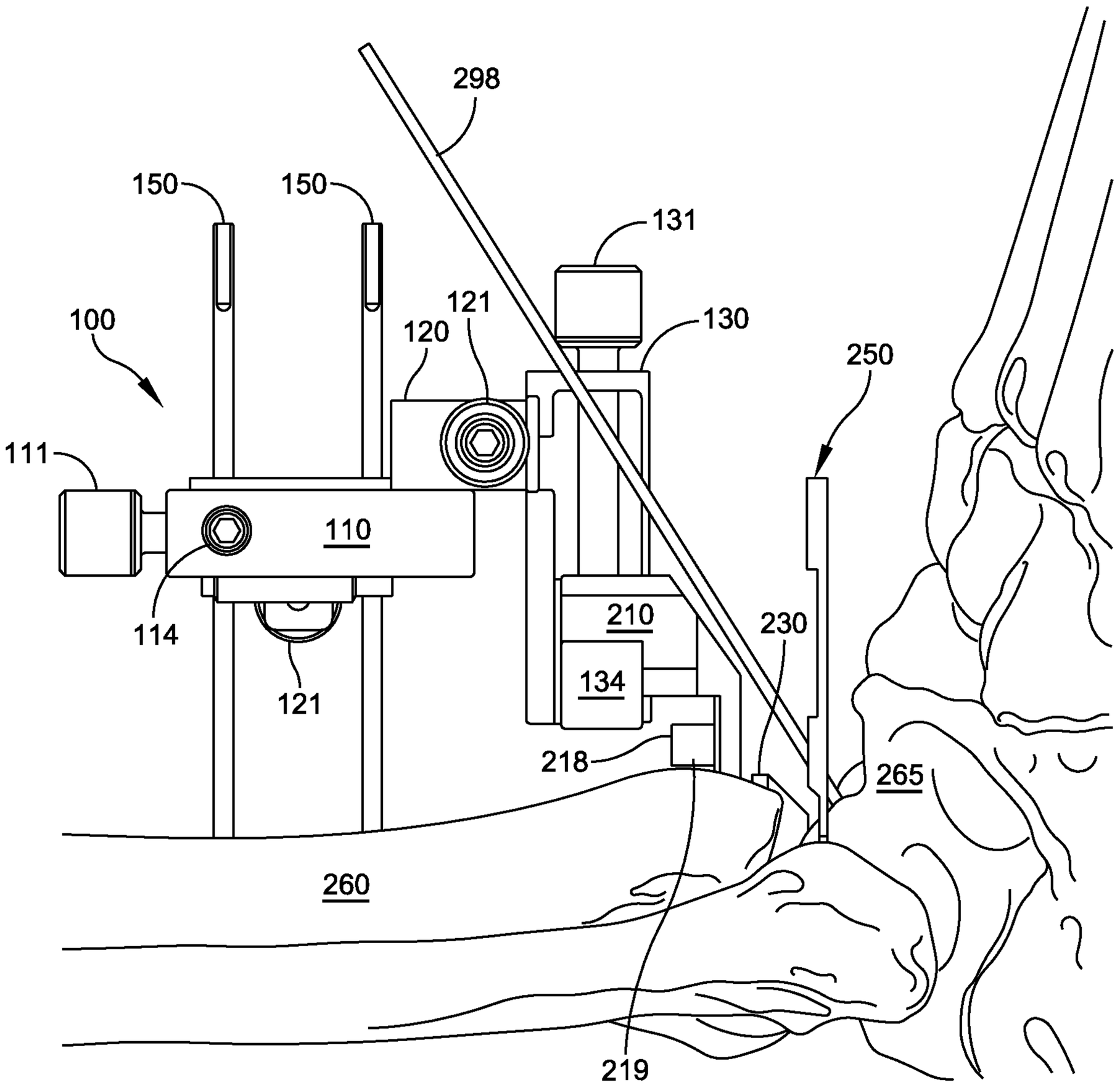
298
150
150
131
121
120
130
100
250
111
110
114
121
210
230
134
218
265
260
219

FIG. 17

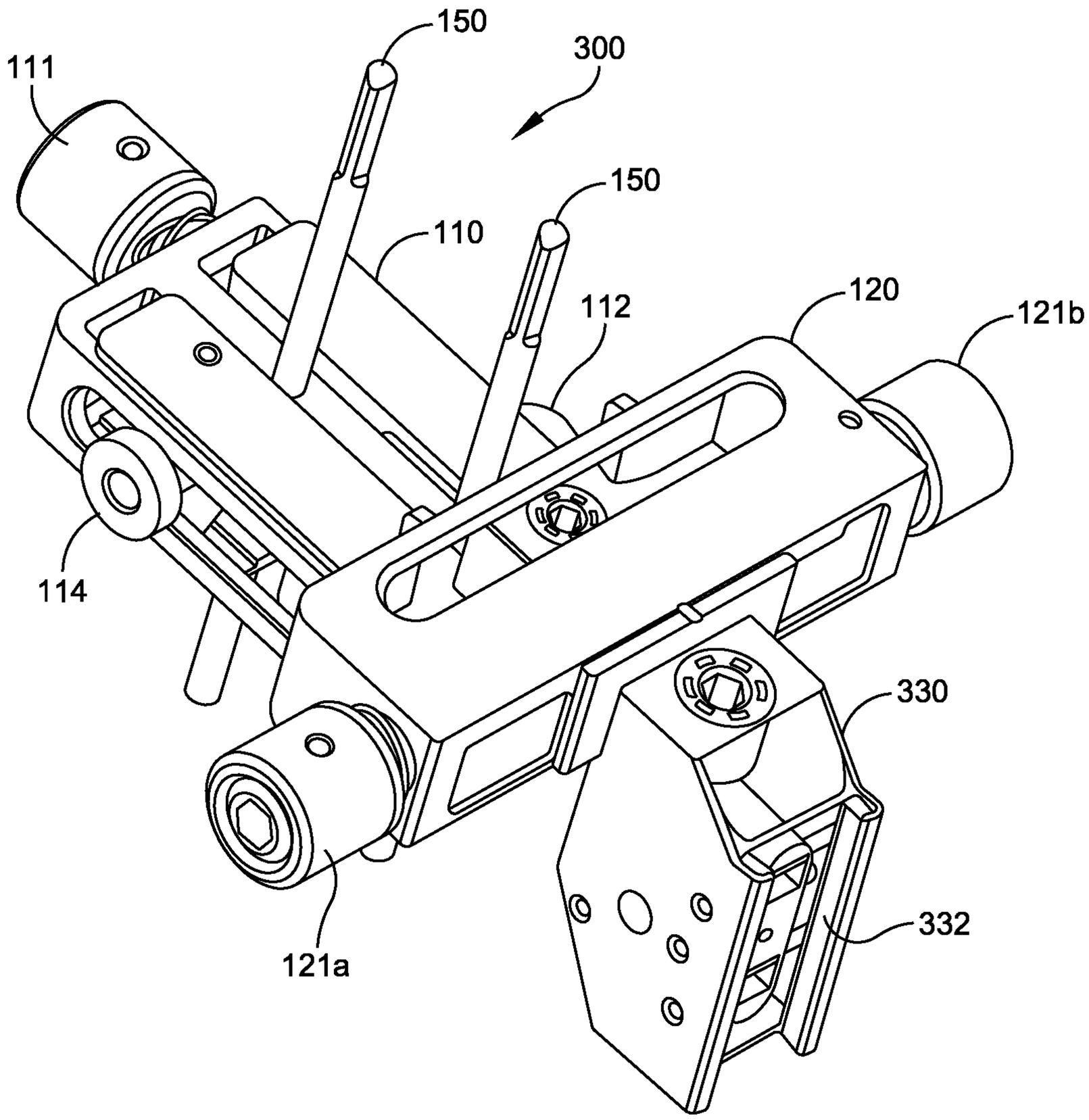

FIG. 18

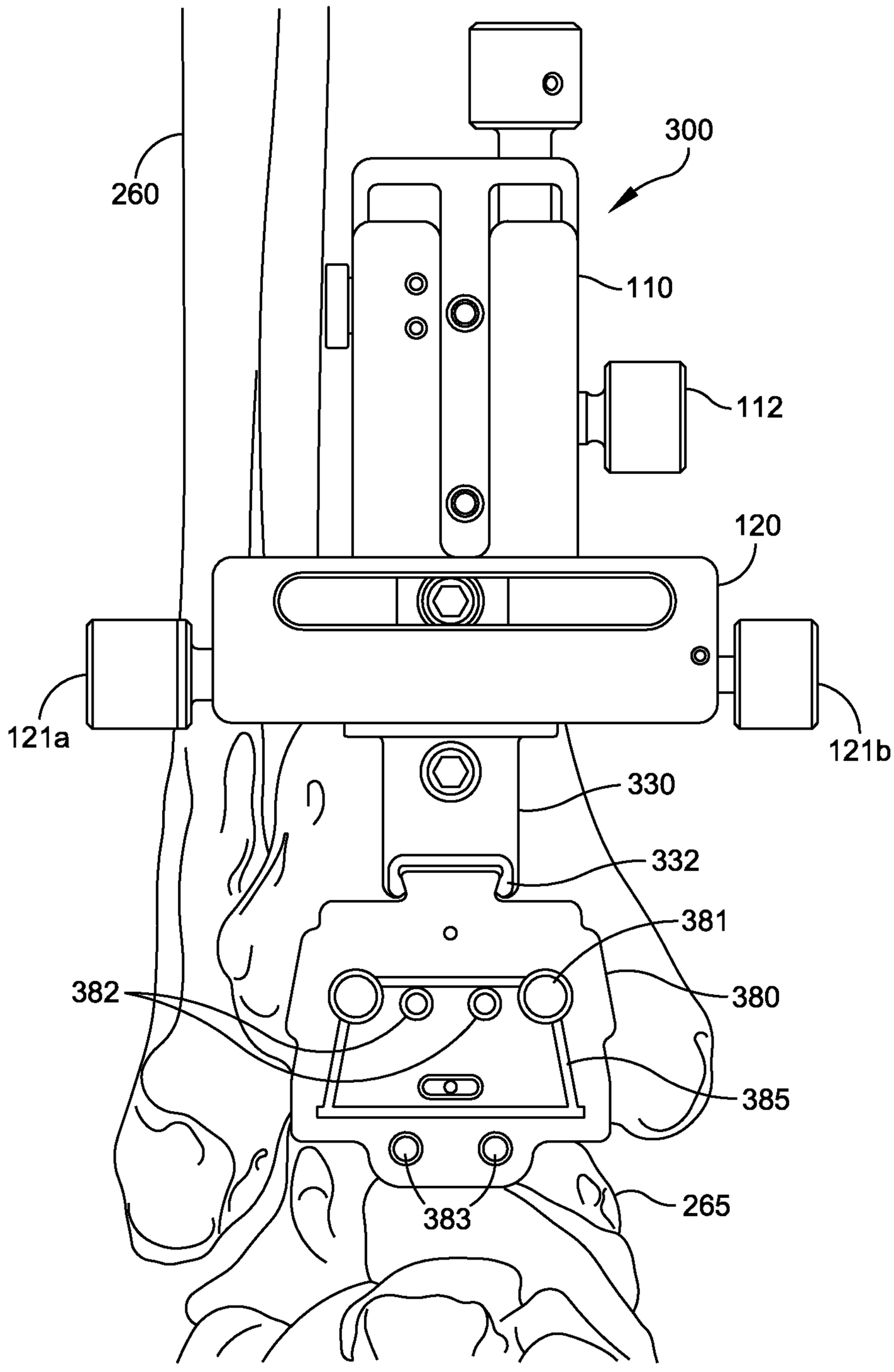

FIG. 19

ANKLE REPLACEMENT SYSTEM AND METHOD

FIELD

This application is a continuation of U.S. patent application Ser. No. 16/405,212, filed May 7, 2019, which is a continuation of U.S. patent application Ser. No. 15/335,949, filed Oct. 27, 2016 (now U.S. Pat. No. 10,321,922) which is a division of U.S. patent application Ser. No. 14/100,799, filed Dec. 9, 2013 (now U.S. Pat. No. 9,480,571), which is a non-provisional of U.S. Patent Application No. 61/746,393, which was filed Dec. 27, 2012, all of which are incorporated herein by reference in their entireties.

This disclosure relates to prosthetics generally, and more specifically to systems and methods for total ankle replacement.

BACKGROUND

The ankle is a joint that acts much like a hinge. The joint is formed by the union of three bones. The ankle bone is the talus. The top of the talus fits inside a socket that is formed by the lower end of the tibia, and the fibula, the small bone of the lower leg. Arthritis, bone degeneration and/or injury can cause ankle joint deterioration resulting in pain, reduced range of motion, and decreased quality of life. In many cases, physicians are recommending ankle replacement surgery with an implant as an option.

Available ankle replacement systems include, for example, the "INBONE"™ system sold by Wright Medical Technologies of Arlington, Tenn. The "INBONE" ™ system includes a talar tray component with stem, which fit into a resectioned distal end of the tibia. A poly insert having a concave distal surface is joined to the tibial tray. A talar dome and stem are implanted in a resectioned proximal end of the talus. The poly insert is configured to articulate with the talar dome.

Associated tools enable the physician to immobilize the foot, while the physician performs appropriate drilling and resectioning of the bones, and implants the prosthetic ankle. An example of such a tool is described in U.S. Pat. No. 7,534,246.

Improved devices and methods are desired.

SUMMARY

In some embodiments, a position adjustment device having a tool holder is locked to at least two pins projecting from respective anterior facing locations near a distal end of a tibia of a patient. The position adjustment device is adjusted. The position adjustment device is locked with the tool holder at first coordinates in the proximal-distal and medial-lateral directions. The distal end of the tibia is resectioned with a tool positioned on the tool holder, while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions. The tool is removed from the tool holder. A tibia trial is placed on the resectioned tibia using the tool holder, while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions. The tibia trial has a size and shape of a tibial tray of an ankle replacement system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of a position adjustment device, or adjustment block suitable for sizing and trialing an implant.

FIG. **2** is an exploded view showing the adjustment block, tibial trial, poly trial insert, and floating trial.

FIG. **3** is an isometric view of the tibia trial of FIG. **2**.

FIG. **4** is an anterior elevation view of the tibia trial of FIG. **3**.

FIG. **5** is a lateral elevation view of the tibia trial of FIG. **3**.

FIG. **6** is an isometric view of the floating trial of FIG. **2**.

FIG. **7** is an isometric view of an adjustment block of FIG. **1**, holding a drilling guide.

FIG. **8** is an isometric view of the adjustment block and drilling guide of FIG. **7**, during the drilling operation.

FIG. **9** is an isometric view of the adjustment block of FIG. **1**, holding a cut guide.

FIG. **10** is an isometric view showing the adjustment block and tibial trial during trial insertion.

FIG. **11** is a lateral side elevation view of the adjustment block and tibial trial during trial insertion.

FIG. **12** is an isometric view showing drilling using the tibia trial to locate peg holes in the distal surface of the tibia.

FIG. **13** shows the tibia and talus after resectioning.

FIG. **14** is an isometric view showing the adjustment block, tibial trial, poly trial insert, and floating trial inserted in the surgical window.

FIG. **15** is a lateral side elevation view of the adjustment block, tibial trial, poly trial insert, and floating trial inserted in the surgical window.

FIGS. **16** and **17** are isometric and lateral side elevation views showing the adjustment block, tibial trial, poly trial insert, and floating trial inserted while the floating trial is being pinned to the talus.

FIG. **18** is an isometric view of an embodiment of the adjustment block providing proximal-distal and medial-lateral adjustments.

FIG. **19** is an anterior top plan view of the adjustment block of FIG. **18**, with a drill guide attached to its tool holder.

DETAILED DESCRIPTION

This description of the exemplary embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written description. In the description, relative terms such as "lower," "upper," "horizontal," "vertical,", "above," "below," "up," "down," "top" and "bottom" as well as derivative thereof (e.g., "horizontally," "downwardly," "upwardly," etc.) should be construed to refer to the orientation as then described or as shown in the drawing under discussion. These relative terms are for convenience of description and do not require that the apparatus be constructed or operated in a particular orientation. Terms concerning attachments, coupling and the like, such as "connected" and "interconnected," refer to a relationship wherein structures are secured or attached to one another either directly or indirectly through intervening structures, as well as both movable or rigid attachments or relationships, unless expressly described otherwise.

FIG. **1** is an isometric diagram of a position adjustment device **100** (also referred to below as an "adjustment block") for positioning of drilling and cutting tools for tibia resectioning, and for tibia trial insertion. The adjustment block **100** provides a common reference location for locating tools and the tibia trial components throughout the sizing, resectioning and trial procedure. In some embodiments, the adjustment block **100** is small enough in profile to position a cut guide into the wound space close to the tibia bone

without applying excess skin tension. The physician can use the adjustment block to position a drill guide and/or cut guide closer to the tibia bone, to make more accurate cuts with less chance of the blade or pins flexing.

The adjustment block **100** has three independently positionable frames **110**, **120**, and **130** for precisely positioning a tool holder **134** adjacent the joint to be replaced.

The first frame **110** is configured to be attached to two fixation pins **150** which have been inserted in the anterior surface of the tibia, near the distal end of the tibia. A locking screw **112** actuates a locking plate (not shown), which bears against the fixation pins **150** to secure the adjustment block **100** relative to the pins. The first frame has a proximal-distal adjustment knob **111** coaxially connected to a screw **113**. The screw **113** can have an Acme thread, trapezoidal thread, square thread or other suitable thread for leadscrew use. The second frame **120** is fixedly attached or unitarily formed with a leadscrew nut (not shown), which the screw **113** drives. Rotation of the proximal-distal adjustment knob **111** rotates screw **113** to advance or retract the second frame **120** in the proximal-distal direction. When the second frame **120** is at the desired proximal-distal coordinate, the physician advances the locking screw **114** to lock the second frame **120** to the first frame **110** in place.

The second frame **120** has at least one medial-lateral adjustment knob **121***a*, **121***b* coaxially connected to a screw **123**. The screw **123** can have an Acme thread, trapezoidal thread, square thread or other suitable thread for leadscrew use. The screw **123** drives a leadscrew nut (not shown), to which the third frame **130** is fixedly attached or unitarily formed with. Rotation of the medial-lateral adjustment knob **121***a* or **121***b* rotates screw **123** to move the third frame **130** in the medial-lateral direction. When the third frame **130** is at the desired medial-lateral coordinate, the physician advances the locking screw **122** to lock the leadscrew **123** of the second frame **120** in place.

The third frame **130** has an anterior-posterior adjustment knob **131** coaxially connected to a screw **133**. The screw **133** can have an Acme thread, trapezoidal thread, square thread or other suitable thread for leadscrew use. The screw **133** drives a leadscrew nut **136**, to which a tool holder **134** is fixedly attached or with which tool holder **134** is unitarily formed. Rotation of the anterior-posterior adjustment knob **131** rotates screw **133** to move the tool holder **134** in the anterior-posterior direction. The tool holder **134** is adapted to hold a drilling tool, a cutting tool, or a tibia trial **210**.

FIG. **2** is an exploded view showing the adjustment block **100**, tibia trial **210**, poly trial insert **230** and floating trial **250**. FIG. **3** is an isometric view of the tibia trial **210**. FIG. **4** is an anterior (rear) elevation view of the tibia trial **210**. FIG. **5** is a sagittal (side) elevation view of the tibia trial **210**.

The tibia trial **210** provides the profile of the tibia tray portion of an ankle replacement system. The tibia trial **210** comprises a plate **211** with a top surface adapted to fit against a distal surface **262** of the resectioned tibia **260**. The plate **211** has a plurality of holes **212** to be used to locate peg holes **263** in the resectioned tibia **260**. The plate **211** has a bottom surface **216** adapted to receive a trial insert, such as a poly trial insert **230**. An anterior tibia reference member **218** extends from the plate **211**. The anterior tibia reference member **218** has a posterior surface **219** adapted to contact an anterior surface **261** of the tibia **260** when the tibia trial **210** is properly positioned. The tibia trial **210** has an anterior mounting portion **213** sized and shaped to be mounted to the tool holder **134** of the adjustment block **100**. In some embodiments, the tibia trial **210** has a notch **217** for aligning an anterior surface of the poly trial insert **230** with the tibia trial **210**. Alignment (or misalignment is readily visible by checking whether the notch **217** is aligned with an edge of the poly trial insert **230**. In some embodiments, the tibia trial **210** is formed of a strong, corrosion resistant material such as stainless steel or a titanium alloy.

The poly trial insert **230** is configured to provide the profile of the poly insert of an ankle replacement system. The poly trial insert **230** comprises a top surface **231** adapted to be detachably mounted to the bottom surface of the plate **216** of the tibia trial **210**. The poly insert **230** has a concave bottom surface **232** with a size and shape of a prosthetic tibia joint surface of the ankle replacement system. The thickness of the poly trial insert **230** matches the poly insert of the ankle replacement system to which the poly trial insert **230** corresponds, allowing verification of the size and thickness of the poly insert using the poly trial insert **230**. In some embodiments, the poly insert of the ankle replacement system has a locking tab to prevent release from the talar tray after surgery; but the poly trial insert **230** has a non-locking tab **233** with a ramped surface, to be detachably inserted in the tibia trial **210** and removed after sizing and resectioning is completed. The non-locking tab **233** fits in a corresponding recess (not shown) in the bottom surface **216** of the tibia trial **210**. The posterior end of the poly trial insert **230** has an undercut **234**, In some embodiments, the poly trial insert **230** is made from the same type of material used in the poly insert of an ankle replacement system. In some embodiments, the poly trial insert **230** is made of a chemical-resistant material such as polyphenylsulfone, which is also referred to as RadelR.

FIG. **6** is an isometric view of the floating trial **250**. The floating trial **250** is configured to provide a contour that matches the contour of the talar dome of the ankle replacement system. The floating trial **250** is configured to be inserted beneath the poly trial insert **230** to contact the concave bottom surface **232** of insert **230**. The floating trial **250** comprises a member **251** having at least one convex anterior surface with a size and shape of a prosthetic talar dome of the ankle replacement system, to permit articulation with the concave surface **232** of the insert. The posterior surface **255** of the member **251** is shaped to match the contour of the resectioned talus. In some embodiments, the floating trial **250** has two convex surfaces **251**. The floating trial **250** further includes a handle portion **252** which is sized to project from the resection site, so the physician can easily optimize the position of the floating trial for smooth articulation with the poly trial insert **230**. The handle **252** of the floating trial **250** has a plurality of pin holes **253** for receiving fixation pins to be used for locating a talar cut guide (not shown). Once the position is optimized, the pins are inserted through the pin holes **253** before completing the resectioning of the talus. In some embodiments, the floating trial **250** is formed of a strong, corrosion resistant material such as stainless steel or a titanium alloy. In some embodiments, the floating trial **250** also has one or more anterior chamfers **254** for reference and alignment.

FIGS. **7-17** show various stages of a method of resectioning and trialing, using the adjustment block **100**, optional drill guide **280**, optional cut guide **290**, tibia trial **210**, poly trial insert **230** and floating trial **250**. This is one example of a use of the devices, but is not limiting.

FIG. **7** shows the adjustment block **100** fixed to the fixation pins **150** (e.g., 3.2 mm pins) which have been inserted in the anterior surface of the tibia **260** near the distal end **261** of the tibia. FIG. **7** also shows a drill guide **280** attached to the tool holder **134** of the adjustment block **100**, with the first frame **110** slightly above the anterior surface of

the tibia **260**. In some embodiments, the tool holder **134** is stage with a pair of pins **135**, and the drill guide **280** has a corresponding pair of mounting ears **283** with holes adapted to snap onto the pins **135**. This tool holder design is just exemplary in nature, and other embodiments include other suitable mounting structures.

In the embodiment of FIG. **7**, the drill guide **280** is a small profile device sized and shaped to be inserted beneath the retracted skin (not shown) in the ankle region. The drill guide **280** has at least two guide holes **281** to be used to drill pilot holes in the tibia **260**. The drill guide also has pin holes **282** that can be used to pin the drill guide to the bone, for position fixation. In some embodiments, the drill guide **280** has sizing patterns **285** showing the size and location of one or more resectioning cuts corresponding to the holes to be drilled using the drill guide **280**. In some embodiments, the drill guide **280** has one or more reference lines **286** that the physician can optionally use to position the drill guide **280** (by adjusting the proximal-distal knob **111**, the medial-lateral knob **121***a* or **121***b*, and the anterior-posterior knob. In some embodiments, the lines **285**, **286** are visible under a fluoroscope, so the physician can view the position and size of the lines **285**, **286** in situ, relative to the patient's bones.

The physician sizes the tibial tray component of the ankle replacement system by mounting a drill guide **280** on the tool holder and adjusting its position as described above. The position adjustment device (adjustment block) **100** is locked with the tool holder **134** at first coordinates in the proximal-distal and medial-lateral directions.

The physician views the X-ray of the tibia bone **260** and drill guide **280** and determines whether it is the optimum size and position for the patient. The position can be adjusted based on the X-ray, using knobs **111**, **121**, **131**. If the size of the resectioning cut corresponding to the drill guide **280** is too large or too small, the physician removes the drill guide, selects a different size drill guide, and snaps the new drill guide onto the tool holder **134** of the adjustment block **100**. The drill guide is then repositioned against the tibia, imaged by fluoroscope, and the size is again checked. To facilitate fluoroscopic X-ray imaging, the drill guide **280** can be made of plastic, while the circles surrounding holes **281** and the patterns **285**, **286** can be made of metal. Thus, only the circles surrounding holes **281** and the patterns **285**, **286** appear on the X-ray, superimposed against the tibia **260** and talus **265**.

Although some embodiments use a single drill guide **280** for sizing, location of fixation pins by holes **282** and drilling corners **281**, other embodiments (not shown) use a first guide (sizing guide) with holes **282** and patterns **285**, **286** for sizing the tibia trial **210** and locating the fixation pins, and a second guide (drilling guide) with holes **281** and **282** for performing the drilling. Because the adjustment block **100** and the pins in holes **282** provide common references, the holes **281** can still be drilled with proper location relative to the pin holes **282** and patterns **285**, **286**.

FIG. **8** shows the tibia **260** with adjustment block **100** and drill guide **280**. Soft tissue is omitted for ease of viewing. When the physician has verified that the optimum size of drill guide **280** has been selected, the physician pins the drill guide **280** to the tibia **260** using (e.g., 2.4 mm) fixation pins **287** inserted through the pin holes **282** and trimmed to extend slightly above the drill guide **280**. Then the physician drills holes in the tibia **260** through the guides holes **281** using the drill guide **280** and drill **288**. The holes thus drilled in the bone **260** define corners of a resectioning cut to be performed in the tibia. The physician then removes the drill guide **280**, while leaving the pins **287** in place (in the distal portion of the tibia **260** to be removed by the resectioning). While removing the drill guide **280**, the adjustment block can remain locked in the first coordinates with the first frame **110** adjusted to the same proximal-distal coordinate and the second frame **120** adjusted to the same medial-lateral coordinate.

FIG. **9** shows the adjustment block **100** still fixed to the fixation pins **150** in the same position, with a cut guide **290** mounted to the tool holder **134** of the adjustment block **100**. The cut guide **290** has a plurality of slots **295**, sized and located to connect the corner holes drilled with the drill guide **280**. The cut guide **290** is sized and shaped to match the drill guide **280**. Thus, the physician has a set of drill guides **280** and a corresponding set of cut guides **290**. The selection of a drill guide size automatically selects the corresponding cut guide size to make cuts which are sized and located to connect the corner holes drilled with the drill guide **280**, as described above. The cut guide **290** has a corresponding pair of mounting ears **293** with holes adapted to snap onto the pins **135**. The cut guide **290** also has pin holes **292** which are sized and located to receive the fixation pins **287**. This aligns the position of the cut guide **290** with the position previously occupied by the drill guide **280**, to ensure alignment of the resectioning cuts with the previously drilled corner holes. In some embodiments, the cut guide **290** includes additional ears **296** with pin holes for receiving additional fixation pins **297**.

To mount the cut guide **290**, the physician slides the holes **292** of cut guide **290** over the fixation pins **287** and snaps the cut guide into place on the tool holder **134**. For stability, the physician can then insert two more fixation pins **297** through the pin holes of ears **296** and into the talus bone **265**. With the cut guide **290** and bones **260**, **265** securely pinned, the physician performs the resectioning cuts through the guide slots **295**, cutting the bone to connect the previously drilled holes. In some embodiments, as shown in FIG. **9**, one cut guide **290** is used for both the tibia resection and the first cut of the talar resection. The cut guide **290** is then removed from the surgery site, and detached from the adjustment block **100**. The sections of the tibia **260** and talus **265** that have been cut are removed, along with the fixation pins **287** and **297**. In other embodiments (not shown), the tibia cut guide is only used to resection the tibia, and a separate cut guide is used to resection the talus after removal of the tibia cut guide.

The use of the adjustment block **100** permits the holes **281** to be drilled first with a first tool, and the cuts to be performed afterwards with a second tool, while maintaining accurate alignment between the holes and the cuts. Drilling the holes first avoids stress concentrations at the corners of the resectioned distal tibia.

Although some embodiments described herein use a drill guide **280** and a cut guide **290** commonly fixed using the adjustment block **100** and fixation pins **287**, other embodiments attach different tools to the tool holder **134** for purpose of resectioning the tibia and talus. For example, some embodiments (not shown) include a cut guide without using a separate drill guide.

Following the initial resectioning, the physician inserts the tibia trial **210**, poly trial insert **230** and floating trial **250**, while the adjustment block **100** is still locked to the two fixation pins **150**, and the tool holder **134** is in the first coordinates in the proximal-distal and medial-lateral directions. Should the physician choose to temporarily remove the adjustment block from the surgery site (e.g., for inspection, cleaning or suctioning), the physician returns the

adjustment block to the same coordinates to locate the tool holder **134** at the same position to complete the procedure. Because the fixation pins **150** are excluded from the distal portion of the tibia removed by the resection, the fixation pins **150** are available throughout the procedure for use in adjusting or correcting the resection cuts.

The physician snaps the tibia trial **210** onto the tool holder **134**. FIGS. **10** and **11** show the adjustment block in position with the tibia trial **210** attached. The adjustment block **100** is adjusted to position the tool holder in an anterior-posterior direction, while the tool holder is at the first coordinates in the proximal-distal and medial-lateral directions. The tibia trial **210** is repositioned in the posterior direction until a predetermined portion of the tibia trail contacts an anterior cortex of the tibia. In some embodiments, the position of the third frame **130** is adjusted until the posterior surface **219** of anterior tibia reference member **218** extending from the plate **211** contacts the anterior cortex of the tibia **260**.

FIG. **12** shows the tibia **260** and talus **265** with the adjustment block and tibia trial **210** in position. The tibia peg drill (not shown) is placed in the head of a tibia peg drill guide **299**, and is inserted in the holes **212** (FIG. **3**) of the tibia trial **210**. The physician drills a plurality (e.g., **3**) peg holes **263** in the distal surface **262** of the resectioned tibia **260** using the tibia peg drill **299**. The holes **212** (FIG. **3**) of the tibia trial **210** are used to locate these holes **263**. FIG. **13** shows the distal end **261** of the tibia **260** at the completion of the peg drilling, with the three peg holes **263** in the resectioned surface **262** of the tibia.

The tibia trial **210** is used to verify size and shape of the resectioning using the tibia trial, prior to implanting the ankle replacement system. Advantageously, the steps of attaching the tibia trial **210** to the tool holder **134**, adjusting the position adjustment device **100** to position the tool holder **134** in an anterior-posterior direction, and placing the tibia trial **210** on the resectioned tibia **260** using the tool holder **134**, can be formed without inserting any additional location fixing pins into the tibia, while the tool holder is locked in the first coordinates in the proximal-distal and medial-lateral directions.

FIGS. **14** and **15** show the adjustment block **100** and tibia trial **210**, after installing the poly trial insert **230** into the tibia trial **210** and positioning the floating trial **250** between the talus **265** and the poly insert trial **230**, to permit articulation with the concave surface **232** of the poly insert trial **230** while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions. The physician can now assess the fit of the ankle replacement system, including size, anterior-posterior position, and whether the tibia has been sized, drilled and cut optimally. If any adjustments are deemed appropriate to the tibia resectioning, the physician can reapply the cut guide with the adjustment block set to the same proximal-distal and medial-lateral coordinates used before.

Referring to FIGS. **16** and **17**, the physician now performs a trial reduction to ensure the correct poly insert height and talus dome position. The talar implant anterior-posterior coordinate is determined by moving the floating trial **250** to the location where it best articulates with the concave surface **232** of the poly trial insert **230**. Two additional fixation pins **298** are inserted through the pin holes **253** of the floating trial **250** using 2 mm K-wire, for example. Additional resection guides (not shown) can be positioned by sliding pin holes in the resection guide(s) over the fixation pins **298**. The remaining two talar cuts are then performed, to match the geometry of the talar dome implant of the ankle replacement system.

A position adjustment device (adjustment block) **100** as described above provides a fixed point of reference that facilitates the AP position of the tibial and talar implants of an ankle replacement system. The adjustment block **100** is capable of fixing a tibial trial **210** via a modular connection **134** to avoid insertion of additional pins in the distal tibia. The tibial trial **210**, while attached to the adjustment block **100**, allows the user to set the tibial implant anterior-posterior position by abutting the anterior post **218** against the tibial bone. The tibial trial **210** also serves as a drill guide to prepare the tibial pegs on the tibial implant.

The tibial trial **210** while rigidly fixed to the adjustment block **100** then translates the anterior-posterior position to the talar trial **250** by using the poly trial insert **230** to articulate with the talar (dome) trial **250**. The talar trial **250** also has chamfer indicators **254** to help the user determine the optimal talar anterior-posterior position.

Advantageously, the system and method described above uses the adjustment block **100** as a fixed reference to associate all other instruments used for trial sizing and trials related to tibial side of the ankle replacement. Thus, a tibial sizer (e.g., drill guide **280**), tibial resection guide (e.g., cut guide **290**), and tibial trial **210** can all be anchored at the same position defined by the adjustment block **100**. This method preserves the distal layer of the tibia to avoid excess pin holes from fixation pins and devices.

The compact size of the adjustment block allows the tools to be fixed and placed close to the surgery site, for more accurate cuts, with reduced chance of components flexing. Sizing guides (e.g., drill guide **280**) and resection guides (e.g. cut guide **290**) can all be placed in the surgical window. The position of the tools and trials can be accurately adjusted by turning the adjustment knobs **111**, **121**, **131** in a small area.

FIGS. **18** and **19** show another embodiment of the adjustment block **300**. The adjustment block **300** has two independently positionable frames **110**, **120** for precisely positioning a tool holder **330** in the proximal-distal and medial-lateral directions, adjacent the joint to be replaced.

The first frame **110** is configured to be attached to two fixation pins **150** which have been inserted in the anterior surface of the tibia, near the distal end of the tibia. A locking screw **112** actuates a locking plate (not shown), which bears against the fixation pins **150** to secure the adjustment block **100** relative to the pins. The first frame has a proximal-distal adjustment knob **111** coaxially connected to a screw **113**. The screw **113** can have an Acme thread, trapezoidal thread, square thread or other suitable thread for leadscrew use. The second frame **120** is fixedly attached or unitarily formed with a leadscrew nut (not shown), which the screw **113** drives. Rotation of the proximal-distal adjustment knob **111** rotates screw **113** to advance or retract the second frame **120** in the proximal-distal direction. When the second frame **120** is at the desired proximal-distal coordinate, the physician advances the locking screw **114** to lock the second frame **120** to the first frame **110** in place.

The second frame **120** has at least one medial-lateral adjustment knob **121***a*, **121***b* coaxially connected to a screw **123**. The screw **123** can have an Acme thread, trapezoidal thread, square thread or other suitable thread for leadscrew use. The screw **123** drives a leadscrew nut (not shown), to which the tool holder **330** is fixedly attached or unitarily formed with. Rotation of the medial-lateral adjustment knob **121***a* or **121***b* rotates screw **123** to move the tool holder **330** in the medial-lateral direction. When the tool holder **330** is at the desired medial-lateral coordinate, the physician

advances the locking screw **122** to lock the leadscrew **123** of the second frame **120** in place.

The position of the tool holder **330** in the anterior-posterior direction is determined by location of the first frame **110** relative to the pins **150**.

The tool holder **330** can have any of a variety of configurations for easily attaching a tool or trial. FIGS. **18** and **19** show a non-limiting example in which the tool or trial is attached to the adjustment block **300** by a dovetail joint **332**. FIG. **19** shows an example of a drill guide **380** adapted for mounting to the dovetail joint **332** of tool holder **330**. The drill guide **380** has corner holes **381** and fixation holes **382**, **383** and sizing patterns **385**. Other tools (e.g., a cut guide) and trials (e.g., tibia trial) can be adapted to fit the tool holder **330**.

Although the subject matter has been described in terms of exemplary embodiments, it is not limited thereto. Rather, the appended claims should be construed broadly, to include other variants and embodiments, which may be made by those skilled in the art.

What is claimed is:

1. System for providing a common reference location for surgical tools comprising:

a tool holder;

at least two pins projecting from respective anterior facing locations near a distal end of a tibia of a patient;

a first frame and a second frame arranged and configured for lockably adjusting a position of the tool holder in the proximal-distal and medial-lateral directions relative to at least one of the at least two pins, wherein a first tool is mounted to the tool holder, the first tool configured for sizing a tibia implant and a second tool mounted to the tool holder, the second tool configured for removing a portion of a tibia bone for acceptance of a tibia implant;

wherein the first frame is coupled to the at least two pins such that a locking screw urges a portion of the frame to bear against the at least two pins so as to secure the tool holder relative to the pins.

2. The system of claim **1**, wherein the first frame includes a proximal-distal adjustment knob coaxially connected to a screw.

3. The system of claim **2**, wherein rotation of the proximal-distal adjustment knob rotates a screw so as to move the second frame in the proximal-distal direction.

4. The system of claim **3**, wherein when the second frame is at a desired proximal-distal coordinate, the second frame is secured with respect to the first frame.

5. The system of claim **1**, wherein the second frame includes at least one medial-lateral adjustment knob coaxially connected to a screw.

6. The system of claim **5**, comprising a third frame such that rotation of the medial-lateral adjustment knob rotates the screw so as to move the third frame in the medial-lateral direction.

7. The system of claim **6** wherein when the third frame is at the desired medial-lateral coordinate, the third frame is secured with respect to the second frame.

8. The system of claim **7** wherein the third frame includes an anterior-posterior adjustment knob coaxially connected to a screw such that rotation of the anterior-posterior adjustment knob moves the tool holder in a anterior-posterior direction.

9. The surgical system of claim **1** comprising a trial configured to be received within a resected first bone, the trial including a plate having a bottom surface defining a channel and a spacer having a body with an extension located at one end, the body being sized and configured to be received within a channel defined by the trial, the extension defining at least first and second holes that are configured to each receive one of the at least two pins.

10. The surgical system of claim **9**, further comprising a cutting guide including a front face defining a plurality of holes and a slot, wherein a first subset of the plurality of holes is configured to each receive one of the at least two pins such that cutting guide is positioned in a first position with respect to a first bone, and wherein a second subset of the plurality of holes is configured to each receive one of the at least two pins such that the cutting guide is positioned in a second position with respect to the first bone that is different from the first position.

11. The surgical system of claim **10**, wherein one of the plurality of holes is a hole that is at least partially threaded for receiving a threaded rod to assist in removing the spacer from the channel defined by the channel.

12. The surgical system of claim **11**, wherein the spacer is formed from a radiolucent material.

13. The surgical system of claim **12**, wherein the first bone is a tibia and the second bone is a talus.

14. A method comprising:

(a) providing a tool holder and at least two pins projecting from respective anterior facing locations near a distal end of a tibia of a patient with a first frame and a second frame arranged and configured for adjusting a position of the tool holder in the proximal-distal and medial-lateral directions relative to at least one of the at least two pins, wherein a first tool is mounted to the tool holder, the first tool configured for sizing a tibia implant and a second tool mounted to the tool holder, the second tool configured for removing a portion of a tibia bone for acceptance of a tibia implant, wherein the first frame is coupled to the at least two pins such that a locking screw;

(b) urging a portion of the frame to bear against the at least two pins so as to secure the tool holder relative to the pins;

(c) locking the tool holder to one of the at least two pins;

(d) adjusting the position of the tool holder in the proximal-distal and medial-lateral directions;

(e) locking the position of the tool holder at a first selected coordinates in the proximal-distal and medial-lateral directions;

(f) resectioning the distal end of the tibia with a tool positioned on the tool holder, while the tool holder is in the first selected coordinates in the proximal-distal and medial-lateral directions;

(g) removing the tool from the tool holder;

(h) placing a tibia trial on the resectioned tibia using the tool holder while the tool holder is in the first selected coordinates in the proximal-distal and medial-lateral directions, the tibia trial having a size and shape of a tibial tray of an ankle replacement system; and

(i) translating the tibia trial in a posterior direction until a predetermined portion of the tibia trial contacts an anterior cortex of the tibia.

15. The method of claim **14**, further comprising verifying size and shape of the resectioning using the tibia trial, prior to implanting the ankle replacement system.

16. The method of claim **15**, further comprising, before step (g):

(i) attaching the tibia trial to the tool holder; and

(ii) adjusting the position adjustment device to position the tool holder in an anterior-posterior direction, while

the tool holder is at the first coordinates in the proximal-distal and medial-lateral directions.

17. The method of claim **14**, wherein steps (g) and (h) are performed in the absence of additional location fixing pins located in the tibia.

18. The method of claim **14**, further comprising:

(i) positioning a drill using the tibia trial; and

(j) drilling at least one peg hole in a distal surface of the resectioned tibia, through at least one hole in the tibia trial.

19. The method of claim **14**, further comprising:

installing an insert into the tibia trial while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions, the insert having a concave surface with a size and shape of a prosthetic tibia joint surface; and

positioning a floating trial adjacent the concave surface of the insert trial while the tool holder is in the first coordinates in the proximal-distal and medial-lateral directions, the floating trial having a convex surface with a size and shape of a prosthetic talar dome.

20. The method of claim **14**, further comprising pinning the floating trial to a talus of the patient, while the floating trial is positioned to permit articulation with the concave surface of the insert trial.

21. The method of claim **20**, wherein the pinning step includes inserting pins through holes in the floating trial, the K-wires being suitable for positioning a guide for resectioning the talus.

22. The method of claim **14**, wherein step (d) includes adjusting at least one adjustment screw to position a connection block in at least one of proximal-distal, medial-lateral and anterior-posterior directions, the connection block adapted to hold the tool or the tibia trial.

23. The method of claim **14**, wherein step (f) includes:

mounting a drill guide on the tool holder;

drilling holes using the drill guide to define corners of a resectioning cut to be performed in the tibia.

24. The method of claim **14**, wherein step (f) further includes:

mounting a cut guide to the tool holder; and

cutting the bone to connect the drilled holes.

25. The method of claim **14**, wherein the tibia trial comprises:

a plate having a top surface adapted to fit against a distal surface of the resectioned tibia, the plate having a plurality of holes to be used to locate peg holes in the resectioned tibia, the plate having a bottom surface adapted to receive an insert;

an anterior tibia reference member extending from the plate, adapted to contact an anterior surface of the tibia when the tibia trial is properly positioned; and

an anterior mounting portion sized and shaped to be mounted to the tool holder.

26. The method of claim **25**, wherein the insert comprises:

a top surface adapted to be detachably mounted to the bottom surface of the plate of the tibia trial;

a concave bottom surface with a size and shape of a prosthetic tibia joint surface of the ankle replacement system.

27. The method of claim **26**, a floating trial is inserted to contact the insert, the floating trial comprising:

a member having at least one convex surface with a size and shape of a prosthetic talar dome of the ankle replacement system, to permit articulation with the concave surface of the insert,

the member having a handle for manual positioning of the floating trial,

the handle having a plurality of holes for inserting pins for locating a talar cut guide.

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